AMENDED IN ASSEMBLY APRIL 1, 2004

CALIFORNIA LEGISLATURE—2003-04 REGULAR SESSION

ASSEMBLY BILL

No. 1957

Introduced by Assembly Members Frommer, Chu, Pavley, and Ridley-Thomas

February 12, 2004

An act to add Article 25 (commencing with Section 4430) to Chapter 9 of Division 2 of the Business and Professions Code, and to add An act to add Sections 14982 and 14983 to the Government Code, and to add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1957, as amended, Frommer. Prescription drugs.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law establishes, within the Department of Consumer Affairs, the California State Board of Pharmacy, which has licensing, regulatory, and disciplinary functions relating to pharmacists, pharmacies, and prescription drugs and devices. Existing law requires the board to impose upon pharmacists and pharmacies fees to fund these functions. The fees are paid into the Pharmacy Board Contingent Fund which is continuously appropriated for the expenses of the board. Existing law provides for the registration and licensure of a nonresident

AB 1957 — 2 —

pharmacy and establishes the fee for an out-of-state drug distributor's license and annual renewal issued pursuant to those provisions.

Existing law provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of and requests for information from the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would require the board department to establish a Web site on or before July 1, 2005, to facilitate the safe purchase by California residents of prescription drugs at reduced prices. It would require that the Web site establish electronic links to pharmacies that are located in Canada and that meet specified requirements. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and Canadian pharmacies that provide mail order service to the United States that meet certification requirements established under the bill and whose Web sites are linked to the department's.

Because the bill would result in increased expenditures from funds that are continuously appropriated to the board by requiring the board to establish a Web site and administer the certification of Canadian pharmacies under the bill, the bill would make an appropriation.

Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.

—3— AB 1957

This bill would require the department to review state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. The bill would require the department to report to the Legislature and recommend options to facilitate prescription drug importation. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from Canada would be made at reduced prices for purposes of state departments and agencies.

Vote: majority. Appropriation: yes no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Article 25 (commencing with Section 4430) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 25. Prescription Drugs

- 4430. (a) The board shall establish a Web site on or before July 1, 2005, that will facilitate the safe purchase by California residents of prescription drugs at reduced prices.
- (b) (1) The Web site shall include price comparisons of the 50 most commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by certified Canadian pharmacies that provide mail order service to the United States.
- (2) (A) The Web site shall establish electronic links to certified Canadian pharmacies.
- (B) The Web site may establish electronic links to other appropriate Web sites to allow California residents to safely purchase prescription drugs at reduced prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.
- (e) For purposes of this section, "certified Canadian pharmacy" means a pharmacy that is located in Canada and meets all of the following requirements as determined by the board:
 - (1) Is licensed by the province in which it is located.

AB 1957 _ 4 ___

- (2) Complies with all of the requirements of a nonresident 1 pharmacy as specified in Section 4112.
 - (3) Meets the safety, access, and affordability standards established by the board for a certified Canadian pharmacy. These standards established by the board shall require, at a minimum, that only a Canadian pharmacy that complies with all of the following may be certified:
 - (A) Requires a prescription from a patient's personal physician.
 - (B) Requires a patient medical history.
 - (C) Requires a signed patient agreement.
- (D) Ships prescriptions in tamper proof original manufacturer 12 13 containers to individuals in the United States.
 - (E) Includes a physical address and pharmacy license number on its company Web site.
 - SEC. 2.

3

4

5

6

8

9

10 11

14

15

16

19

21 22

24

25

26

27

28

29

32

34

- SECTION 1. Section 14982 is added to the Government Code, 17 18 to read:
 - 14982. (a) The department shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. State departments to be reviewed shall include, but not be limited to, all of the following:
 - (1) The State Department of Health Services.
 - (2) The Managed Risk Medical Insurance Board.
 - (3) The Department of General Services.
 - (4) The California Public Employees' Retirement System (CalPERS).
- (b) The department shall report its findings based on the review 30 required under subdivision (a) to the Legislature and shall recommend options to the Legislature, including conducting pilot programs, to facilitate prescription drug importation. The recommendations shall include a determination of the need to seek any federal approvals or waivers.
- 35 SEC. 3.
- *SEC.* 2. Section 14983 is added to the Government Code, to 36 37 read:
- 14983. (a) The department may establish pilot programs 38 under which purchases of prescription drugs from Canada are

5 AB 1957

made at reduced prices for purposes of state departments and agencies.

- (b) As a condition of implementing any pilot program under this section, the department shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.
- SEC. 3. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

9 10 11

2

3

5 6

8

Article 5. Prescription Drug Web Site

12 13

14

15

16

17

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

- 110242. (a) The department shall establish a Web site on or before July 1, 2005, that will facilitate the safe purchase by California residents of prescription drugs at reduced prices.
- (b) (1) The Web site shall include price comparisons of the 50 most commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by Canadian pharmacies that provide mail order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).
- (2) (A) The Web site shall establish electronic links to pharmacies that are located in Canada and that meet the following requirements:
 - (i) Are licensed by the province in which they are located.
- (ii) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, as determined to be appropriate by the department.
 - (iii) Require a prescription from a patient's personal physician.
 - (iv) Require a patient medical history.
 - (v) Require a signed patient agreement.
- (vi) Ship prescription drugs in tamper proof original manufacturer containers to individuals in the United States.
- (vii) Include a physical address and pharmacy license number on its company Web site.
- (viii) Sell only prescription drugs that have been approved for sale in Canada by the Therapeutic Products Directorate of Health Canada.

AB 1957 —6—

3

4

(ix) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription

(B) The Web site may establish electronic links to other 5 appropriate Web sites to allow California residents to safely 6 purchase prescription drugs at affordable prices, including links 7 to Web sites of health plans and health insurers regarding their 8 prescription drug formularies.